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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Braun *et al.*

Serial No. 09/687,483

Confirmation No.:

Filed: October 13, 2000

For: METHODS FOR GENERATING  
DATABASES AND DATABASES FOR  
IDENTIFYING POLYMORPHIC  
GENETIC MARKERS

Art Unit: 1631

Examiner: Clow, Lori A.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Date of Deposit: July 10, 2002

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*Alicia Bradbury*  
Alicia Bradbury

TRANSMITTAL OF PETITION UNDER 37 C.F.R. §1.144

Commissioner for Patents  
P. O. Box 2327  
Arlington, VA 22202

Dear Sir:

Transmitted herewith are a Petition from Requirement for Restriction under 37 C.F.R. §1.144, responsive to the Office Action mailed May 13, 2002; a check in the amount of \$130 for the Petition fee; and a return postcard. If a Petition for extension of time is needed, this paper is to be considered such Petition.

- ☒ The Commissioner is hereby authorized to charge the deficiency in the above check and any fee that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,  
HELLER EHRMAN WHITE & MCAULIFFE LLP

By:

*Stephanie L. Seidman*  
Stephanie L. Seidman  
Registration No. 33, 779

Attorney Docket No. 24736-2033  
Address all correspondence to:  
Stephanie L. Seidman, Esq.  
HELLER EHRMAN WHITE & MCAULIFFE LLP  
4350 La Jolla Village Drive  
San Diego, CA 92122-1246  
Telephone: 858 450-8400  
Facsimile: 858 587-5360  
e-mail: sseidman@HEWM.com



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Braun *et al.*

Serial No. 09/687,483

Confirmation No.: 7859

Filed: October 13, 2000

For: METHODS FOR GENERATING  
DATABASES AND DATABASES FOR  
IDENTIFYING POLYMORPHIC  
GENETIC MARKERS

Art Unit: 1631

Examiner: Clow, Lori A.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Date of Deposit: July 10, 2002

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U.S. Patent and Trademark Office  
P. O. Box 2327  
Arlington, VA 22202

*Alicia Bradbury*  
Alicia Bradbury

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PETITION UNDER 37 C.F.R. § 1.144  
PETITION FROM REQUIREMENT FOR RESTRICTION

Commissioner for Patents  
P. O. Box 2327  
Arlington, VA 22202

Dear Sir:

Applicant hereby petitions under 37 C.F.R. § 1.144 from a Requirement for Restriction and a Requirement for Election of Species in the above-captioned application. Applicant respectfully requests reconsideration and removal of the Restriction Requirement as between Groups II and V and between Groups II and XVI, and petitions for combining the claims of Groups II, V and XVI for examination in this application. Further, Applicant petitions for removal of the Requirement for Election of Species within the elected Group II.

STATEMENT OF FACTS

The Restriction Requirement, mailed September 21, 2001, sets forth sixteen (16) Groups. Applicant elected, with traverse, Group II in an Election, mailed March 18, 2002. Applicant requested reconsideration of the Restriction Requirement as between Groups II and V, and as between Groups II and XVI. The Examiner deemed Applicant's arguments unpersuasive, and the Restriction Requirement was made final in an Office Action mailed May 13, 2001.

## ARGUMENT

### RESTRICTION REQUIREMENT

Applicant respectfully petitions for reconsideration and removal of the Restriction Requirement as between Groups II and V, and as between Groups II and XVI, in view of the following remarks. The Office Action, mailed September 21, 2001, urges that the Restriction Requirement is based on the allegation that the various Groups are patentably distinct. Applicant respectfully submits that Group II is related to each of Groups V and XVI as subcombination/combination for which a showing of two-way distinctness is required. Such showing has not been made.

#### **Restriction Between Groups II and V**

Group II, claims 4-17, 30-31, 43-54, and 98-99, includes claims directed to a database containing datapoints representative of a plurality of healthy organisms, and is restricted further to an election of species to one of the parameters contained in claim 9. Group V, which includes claims 32-42, includes claims directed to a system for high throughput processing of biological samples that includes an automated process line, a data analysis system, a control system, and a database of claim 8 (Restriction Group II). Hence, Group II is related to Group V as a combination/ subcombination, where the system is the combination and the database is the subcombination. A showing of two-way distinctness is required for groups related as a combination/ subcombination.

Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only** if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 806.05(c), paragraphs 1 and 3.

Group II includes claims directed to a database. For example claim 8 of Group II is directed to:

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8. A database, comprising:  
datapoints representative of a plurality of  
healthy organisms from whom biological samples are  
obtained,  
wherein each datapoint is associated with data  
representative of the organism type and other identifying information.

Group V includes claims directed to a system for high throughput processing.  
For example, claim 32 of Group V is directed to:

32. A system for high throughput processing of biological samples, comprising:  
a process line comprising a plurality of processing stations, each of which performs a procedure on a biological sample contained in a reaction vessel;  
a robotic system that transports the reaction vessel from processing station to processing station;  
a data analysis system that receives test results of the process line and automatically processes the test results to make a determination regarding the biological sample in the reaction vessel;  
a control system that determines when the test at each processing station is complete and, in response, moves the reaction vessel to the next test station, and continuously processes reaction vessels one after another until the control system receives a stop instruction; and  
a database of claim 8, wherein the samples tested by the automated process line comprise samples from subjects in the database.

In this instance, the combination, the system of claim 32, includes the database of Group II and a known automated process line (see page 40 of the instant specification which states: "[t]he computers and databases can be used in conjunction, for example, with the APL system (see copending U.S. application Serial No. 09/285,481), which is an automated system for analyzing biopolymers"). Hence, absent evidence to the contrary, Group V, the combination, requires the particulars of the database of Group II, the subcombination, for patentability. Example II of MPEP 806.05(c) states:

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If there is no evidence that [the] combination...is patentable without the details of [the subcombination], restriction should not be required. Where the relationship between the claims is such that the separately claimed subcombination...constitutes the essential distinguishing feature of the combination...as claimed, the inventions are not distinct and a requirement for restriction must not be made, even though the subcombination has separate utility.

Therefore, as between Group II and Group V restriction is **not** proper.

The Examiner found applicant's traversal unpersuasive, stating in the Office Action mailed May 13, 2002 that "the system for high throughput processing of biological samples [of Group V] does not necessarily have to be utilized to analyze the [claimed] biomarkers" and the claimed subject matter "could be practiced without the system of high throughput analysis, for example by traditional serum level analysis."

The Examiner's assertion does not appear to address either prong of the two-way distinctiveness test required for restriction of subject matter related as subcombination/combination. As demonstrated, the subject matter of Groups II and V is related by the database of Group II. Claim 8 of Group II is directed to a database. Claim 32 of Group V is directed to a system that includes the database of claim 8, and one cannot practice the claimed subject matter of claim 32 and its related claims without the database.

It is respectfully submitted that the Examiner has not complied with the requirements for restriction as outlined in MPEP 806.05(c), and has not shown that the combination does not require the subcombination to be patentable. Therefore, applicant contends that restriction is not proper and petitions for removal of the Restriction Requirement as between Groups II and V.

#### **Restriction Between Groups II and XVI**

It is respectfully submitted that the Restriction Requirement as between Groups II and XVI is improper because the Groups are not patentably distinct, for essentially the same reasons as discussed above. Group II, the

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subcombination, includes claims directed to a database containing datapoints representative of a plurality of healthy organisms. Group XVI, the combination, is directed to a system for high throughput processing of biological samples that includes a database of Group II. For example, claim 100, in Group XVI, recites:

A system for high throughput processing of biological samples, comprising:

**a database of claim 8**, wherein the samples tested by the automated process line comprise samples from subjects in the database; and

a mass spectrometer for analysis of biopolymers in the samples.

Thus, claim 100 is directed to a combination that includes a database of claim 8, the subcombination. Because Group XVI is directed to the combination of the database of claim 8 and a mass spectrometer, and a mass spectrometer is not a basis for patentability, Group XVI requires the particulars of the database of claim 8 from Group II for patentability. Thus, the combination as claimed requires the subcombination as claimed for patentability. Therefore, as between Group II and Group XVI, restriction is **not** proper.

The Examiner's assertion that the claimed subject matter "could be practiced without the system of high throughput analysis, for example by traditional serum level analysis," is not correct. The assertion does not address the issue of distinctness. Claim 100, which is directed to a combination that includes a database of claim 8 as the subcombination, is specifically directed to a system for high throughput analysis for processing of biological samples that employs a database of Group II.

#### **Obviousness-Type Double Patenting**

Applicants respectfully submit that if this division of claims is maintained, applicant ultimately could be granted multiple patents that include claims with overlapping subject matter. For example, claims 8, 32, and 100 (discussed above) could ultimately end up in different patents. If claim 8 issues first,

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obvious-type double patenting between claims 8 and 32 or between 8 and 100 in a later issuing patent could not be held. MPEP 806, paragraph 3 states:

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Since, if restriction is required by the Office double patenting cannot be held, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C.121, third sentence, provides that wherein the Office requires restriction, the patent of either the parent or any divisional application thereof conforming to the requirement cannot be used as a reference against the other. This apparent nullification of double patenting as ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same inventions in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

Applicant, thus, ultimately could obtain multiple patents with different expiration dates that include claims with overlapping subject matter. The Office would be precluded from requiring terminal disclaimers.

In light of the above arguments, applicant petitions for removal of the restriction requirement as between Groups II and V and Groups II and XVI.

#### **REQUIREMENT FOR ELECTION OF SPECIES**

Applicant petitions for removal of the Requirement for Election of Species for the elected claims. Elected Group II, which includes claims 4-17, 30-31, 43-54, and 98-99, includes claims directed to a method of producing "healthy patient" databases, which include as datapoints the answers that healthy patients give to various questions. The subjects of the database are "healthy" subjects; it is the selection of such subjects as the source of data for a database that is a subject of the application and claimed subject matter. The Examiner has imposed an election of species, requiring the selection of one of the parameters or datapoints contained in claim 9.

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Election of species is a search tool intended to be used where there is a generic claim that encompasses a large number of species, such as a claim that sets forth a formula for an organic compound that includes numerous compounds, each of which has a large number of possible alternatives. In such instance, it is impossible to search all of the combinations and permutations of the alternative compounds encompassed within the scope of the claims, and the applicant is entitled to have a reasonable number of species searched.

In this instance, the subject matter for which a search would be conducted is a database as claimed, not the datapoints that constitute the database. The claims are directed to databases and methods of using databases that include sets of parameters associated with healthy subjects in populations. The parameters include ethnicity, age, sex, medical history, and ultimately genotypic information, and are input into and stored in the database. The database can then be sorted according to these parameters.

Applicant respectfully submits that the requirement for election of a single parameter of instant claim 9 as a "species" is inconsistent with the subject matter of the instant claims. A database composed of a single parameter or type of datapoint could not be sorted by parameter if only one parameter is contained therein. Moreover, such requirement could violate applicant's right to have all species that form a single general inventive concept included in a single application (see, MPEP 1893.03(d)).

### **CONCLUSION**

In view of the above, applicant petitions for removal of the restriction requirement as between Groups II and V and between Groups II and XVI. It is respectfully submitted that the restriction requirement as between Groups II and V and Groups II and XVI is improper because Group II is related to Group V and to Group XVI as a combination/subcombination for which a showing of two-way distinctness is required. The Groups are not patentably distinct because the



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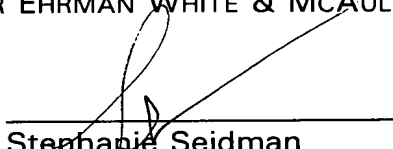
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combination requires the subcombination as claimed in order to be patentable. Because applicant has elected Group II, with traverse, in the instant application, applicant hereby petitions that Groups II, V and XVI (claims 4-17, 30-54, and 98-100) be combined for examination herein. Further, for the above reasons, applicant petitions for removal of the Requirement for Election of Species in Group II.

\* \* \*

Respectfully submitted,  
HELLER EHRMAN WHITE & MCAULIFFE LLP

By:

  
Stephanie Seidman  
Registration No. 33,779

Attorney Docket No. 24736-2033

**Address all correspondence to:**

Stephanie Seidman, Esq.

HELLER EHRMAN WHITE & MCAULIFFE LLP

4350 La Jolla Village Drive, 6th Floor

San Diego, California 92122-1246

Telephone: 858 450-8400

Facsimile: 858 587-5360

email: sseidman@HEWM.com